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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,431	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004 and 07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges the amendments received 10 July 2006. Claims 1-62 are pending.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. In view of the amendments to the claims and in view of the persuasive arguments of the applicant, see "Remarks," pages 14-16, the examiner withdraws the rejection of claims 1-6, 8-9, 11-12, 14-32, 34-44, 46-53, 55 and 58-62 under 35 U.S.C. 102(b) as being anticipated by Ideker et al (U.S. 6,205,357).

4. Claims 1-3, 5-8, 11-13, 16-23, 25-30, 32-38, 42, 44-46, 49-51, 52-53, 55 and 58-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Infinger (U.S. 5,527,345). Regarding claims 1-2, 8, 19-20, 22-23, 38 and 58, Infinger discloses (col. 5, lines 1-14) an "atrial defibrillator (30) generally includes an enclosure (32) for hermetically sealing the internal circuit elements of the atrial defibrillator to be described hereinafter, an endocardial first lead (34), and an intravascular second lead (36). The enclosure and first and second leads are arranged to be implanted beneath the skin of a patient so as to render the atrial defibrillator fully implantable. The endocardial first lead preferably comprises an endocardial bi-polar lead having electrodes (38 and 40) arranged for establishing electrical contact with the right ventricle (12) of the heart (10). The electrodes permit bi-polar sensing of ventricular activations in the right ventricle. The

electrodes further provide for pacing the ventricles (12 and 14)." The examiner considers this to be an implantable housing, a first electrode coupled to the housing and a second electrode. The examiner considers the system to inherently have a lead interface coupled to the housing, since there are leads connected to the housing. Within the enclosure (col. 5, lines 48-57) "the atrial defibrillator includes a first sense amplifier (50), a second sense amplifier (52), and an R wave detector (54). The first sense amplifier forms a first detecting means (48) which, together with the lead (36) to which sense amplifier (50) is coupled, senses atrial activity of the heart. The second sense amplifier and the R wave detector form a second detecting means (51) which, together with the lead (34) to which sense amplifier (52) is coupled, detects ventricular activations of the right ventricle of the heart." The examiner considers this to be monitoring circuitry coupled to the first and second electrodes, the first and second electrodes configured for cardiac activity sensing when the device is operated in a monitoring mode. The atrial defibrillator also includes a (col. 6, lines 50-58) "a charger and storage capacitor circuit (74) of the type well known in the art which charges a storage capacitor to a predetermined voltage level, a discharge circuit (76) for discharging the storage capacitor within circuit during a predetermined discharge time to provide a controlled discharge output of electrical energy, when required, to the atria of the heart, and a pacer (82) for applying pacing electrical energy to the ventricles of the heart." The examiner considers this to be energy delivery circuitry coupled to the first and second electrodes, the first and second electrodes configured for cardiac activity sensing and energy delivery when the

device is operated in an energy delivery mode. Infinger further discloses (col. 6, lines 3-10) the atrial defibrillator includes a microprocessor (62), the operation of which controls stages, including "an enable/disable stage (64), an interval timer stage (66), a counter stage (68), an atrial arrhythmia detector in the form of an atrial fibrillation detector (70), and a charge delivery and energy control stage (72)." The examiner considers this to be a controller coupled to the lead interface, monitoring circuitry, and energy delivery circuitry. The microprocessor, (col. 7, lines 40-45) ", through the enable/disable stage, enables the pacer output and escape interval timer over control line. This begins the post-cardioversion demand pacing of the heart. Pacing of the heart is enabled for a finite time until the occurrence of a predetermined event." The examiner considers this to be the controller transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry is disabled, to the energy delivery mode, in which the energy delivery circuitry is enabled. The examiner further considers that since the device would have to be properly connected to the lead in order to sense cardiac activity, the system inherently transitions at least in part in response to coupling the cardiac lead to the lead interface.

5. Regarding claim 3 and further regarding claim 8, Infinger discloses (col. 7, lines 13-17) "the microprocessor enables the sense amplifier (52) and R wave detector, over control line (87) and sense amplifier (50) and the analog to digital converter (60) to acquire data representative of the activity of the heart which is stored in the aforementioned memory."

6. Regarding claims 5, 7, 13, 16, 33-34, 51, 59 and 61, Infinger discloses, (col. 8, lines 33-42) "a solid state switch may be employed between the battery (80) and each of the pacer output (84), the escape interval timer (86), the sense amplifier (52), and the R wave detector (54). When the pacer (82) is disabled, the control lines (87 and 89) will turn the solid state switches off to effectively disconnect these circuits from the battery. When these circuits are enabled, the control lines will turn the solid state switches on to connect the circuits to the battery. When the pacer is disabled, only the leakage current through the solid state switches will consume power." The examiner considers this to be a mode switch coupled to the controller, the mode switch configured to transition the cardiac device between the monitoring mode and the energy delivery mode.

7. Regarding claims 6, 11-12 and 35-36 and further regarding claim 38, Infinger discloses (col. 6, lines 30-40) an "external controller (100) is arranged to communicate with a receiver/transmitter (102) which is coupled to the microprocessor over a bi-directional bus (104)." The receiver/transmitter conveys "various information which it obtains from the microprocessor to the external controller or for receiving programming parameters from the external controller which the receiver/transmitter then conveys to the microprocessor for storage in internal memory or in the aforementioned external memory within enclosure." The examiner considers this to be a transceiver that receives a transmit request signal and transmits the contents of the memory to a patient-external device in response to receipt of the transmit request signal.

8. Regarding claims 17, 35 and 60, Infinger discloses, (col. 8, lines 24-32) "for enabling and disabling the pacer, the bias voltage on the pacer output (84), escape interval timer (86), sense amplifier (52) and R wave detector may be switched between a low bias voltage, rendering these circuits disabled and inoperative, to a regular bias voltage, to effectively provide power to these circuits for rendering these circuits enabled and fully operative. In the disabled state, these circuits would consume little if any measurable power to conserve the battery (80)." The examiner considers this to be a software switch configured to switch the cardiac device between the first operating mode and the second operating mode.

9. Regarding claim 18, Infinger discloses, (col. 7, lines 18-23) "the atrial fibrillation detector (70) then processes the stored data to determine if the heart is experiencing an episode of atrial fibrillation. If atrial fibrillation is detected, the charge delivery and control stage initiates the storage of the cardioverting electrical energy within the storage capacitor of charger and storage capacitor circuit (74)." The examiner considers this to be detection circuitry configured to select signals associated with cardiac arrhythmic events as the selected cardiac signals for storage.

10. Regarding claim 21, Infinger discloses (col. 4, lines 1-10) the use of cardioversion/defibrillation therapy.

11. Further regarding claim 23, since the leads are connected to the atrial defibrillator and headers are generally accepted as connection means, the examiner considers the device to contain a header.

12. Regarding claims 25-30 and 33, since the leads are connected to the atrial defibrillator, the examiner considers the first and second electrode to be coupled to the housing using the same means (header) that are used to connect the leads to the device housing. The cardiac lead is also connected to the therapy circuitry within the housing using this means.

13. Regarding claim 32, the examiner considers that processor memory inherently contains code. Providing the memory contains a mode switch feature, which Infinger's system does, that code would actuate the mode switch.

14. Regarding claims 42, 44-45, 49-50, 52-53 and 55, in view of the structure as disclosed by Infinger, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. In view of the amendments to the claims and in view of the persuasive arguments of the applicant, see "Remarks," page 16, the examiner withdraws the rejection of claims 7 and 13 35 U.S.C. 103(a) as being unpatentable over Ideker et al (U.S. 6,205,357) in view of Funke (U.S. 4,312,355); and of claims 10, 54 and 56-57 as being unpatentable over Ideker et al (U.S. 6,205,357).

17. Claims 4, 14-15, 31, 39-41, 43, 48 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infinger (U.S. 5,527,345) in view of Ideker et

al (U.S. 6,205,357). Regarding claims 4, 14-15 and 41, Infinger discloses the claimed invention except for a programmable filter coupled to the detection circuitry. Ideker however discloses (col. 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD (40). Amplification and bandpass filtering are followed by sensed event detection." Infinger and Ideker both disclose devices for switching between sensing and stimulating modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Infinger's mode-switching and therapy-disabling system with Ideker's programmable filter in order to eliminate any noise from the sensed signal and prevent a misdiagnosis.

18. Regarding claims 31 and 48, Ideker discloses, (col. 11, lines 40-49) "the electronic circuit (215) also includes a cardiac cycle monitor ("synchronization monitor 272") for providing synchronization information to the controller. As discussed below, the synchronization is typically provided by sensing cardiac activity in the RV, but may also include other sensing electrodes which can be combined with the defibrillation electrodes or employed separately to provide additional assurance that defibrillation shock pulses are not delivered during sensitive portions of the cardiac cycle so as to reduce the possibility of inducing ventricular fibrillation." The examiner considers this to be a lead capable of providing resynchronization pacing therapy.

19. Regarding claims 39-40, 43 and 62, Ideker discloses (column 12, lines 8-11) "the defibrillation pulses may be triggered by an external signal administered by a physician, with the physician monitoring the patient for the appropriate time of administration." The examiner considers this to teach a trigger that is capable of being actuatable by a patient to perform the claimed functions.

20. Claims 9-10, 24, 47, 54 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infinger (U.S. 5,527,345). Infinger discloses the claimed invention but does not disclose expressly the first and/or second electrode provided in or on the housing. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the electrodes electrically coupled to the housing as taught by Infinger, with the electrodes in or on the housing, because the applicant has not disclosed this placement of the electrodes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the electrodes coupled to the housing using leads as taught by Infinger, because the signals sensed by the electrodes are able to be analyzed by the device, and therapy to be delivered from the device is able to be delivered to the electrodes using leads. Therefore, it would have been an obvious matter of design choice to modify Infinger's electrode arrangement to obtain the invention as specified in the claims.

21. Regarding claim 47, Infinger discloses the claimed invention but does not specifically mention that the cardiac stimulation therapy comprises an antitachycardia pacing (ATP) therapy. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Infinger's pacing therapy with ATP therapy in order to prevent or stop tachycardia if sensed by the system.

22. Regarding claim 54, Infinger discloses the claimed invention but does not disclose expressly the updating a software program. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the software switch as taught by Infinger, with the updating of the software switch, because the applicant has not disclosed the updating provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the bias voltage switch as taught by Infinger, because this method is capable of switching the device between enabled and disabled modes. Therefore, it would have been an obvious matter of design choice to modify Infinger to obtain the invention as specified in the claim.

23. Regarding claims 56-57, Infinger discloses the claimed invention but does not disclose expressly the use of an epicardial lead or a subcutaneous lead. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the endocardial lead as taught by Infinger, with the epicardial or subcutaneous lead, because the applicant has not disclosed that either of

these leads provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead implanted in the superior or inferior vena cava as taught by Infinger, because the leads connect the electrodes to the housing in order to pace or sense the heart. Therefore, it would have been an obvious matter of design choice to modify the lead configuration to obtain the invention as specified in the claims.

Allowable Subject Matter

24. The indicated allowability of claims 33 and 45 is withdrawn in view of the newly discovered reference to Infinger (U.S. 5,527,345). Rejections based on the newly cited reference are above.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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